Sunset Public Hearing Questions for
Tennessee Medical Lab Board
Created by Section 68-29-109, *Tennessee Code Annotated*
(Sunset Termination June 2022)

Enabling Statute, Purpose, and Rules and Regulations

1. Please provide a brief introduction to the board including information about its purpose, statutory duties, staff, and administrative attachment.

   The Medical Laboratory Board ("the Board") was created in 1990 by an act of the State legislature. The designated mission of the Board is the same as the Department of Health's mission to protect, promote, and improve the health and prosperity of people in Tennessee. Tennessee with the establishment of requirements for the operation and oversight of the practice of laboratory medicine. Board members provide the interpretation of laws, in the form of rules, and regulations relative to the elevated practice standards applied within the medical laboratory arena. The Board is authorized to issue licenses to qualified candidates who have met the appropriate guidelines in education, training, and national certification requirements pertaining to the professions. The Board also issues licenses to facilities who house the practice of laboratory medicine in a physical location to include hospital laboratories, independent laboratories, blood donor centers, plasmapheresis centers, ambulatory treatment surgery centers, esoteric laboratories, and molecular diagnostic centers. Medical laboratories are charged with providing the medical practitioner vital information essential in the determination of the nature, extent, cause, and condition of individuals seeking medical treatment.

2. Has the board promulgated rules and regulations in accordance with Section 69-29-105? If yes, please cite the reference(s).

   Yes. Rules and Regulations governing Medical Laboratory Personnel 1200-06-01 were revised July 2010. Rules and Regulations for the Training Programs of Medical Laboratory Personnel 1200-06-02 were revised in January 2015. Rules and Regulations Governing Medical Laboratories section 1200-06-03 were revised June 2015.

Board Organization

3. Provide a list of current board members and explain how membership complies with Section 68-29-109, *Tennessee Code Annotated.*

Member	Representation	Term Beginning	Term Ending	Consecutive	Demographics
LeeAnne Briggs, MT	Educator	01/01/2019	12/31/2022	Yes	Under 60 years, Non-Minority, Female, East
Carla Davis, MD	Pathologist	04/03/2014	12/31/2021	Yes	Over 60 years, Non-Minority, Female, Middle
Danielle Gibson, MD	Pathologist	01/09/2019	12/31/2022	Yes	Under 60 years, Non-Minority, Female, Middle
Michael Johnson, MT	Medical Technologist	05/04/2015	12/31/2023	Yes	Under 60 years, Non-Minority, Male, Middle
Gaye Jolly, MT	Hospital Administrator	11/18/2015	12/31/2021	Yes	Over 60 Years, Non-Minority, Female, East
Lynn Stewart	Public Member	11/16/2018	12/31/2021	Yes	Over 60 years, Minority, Female, Middle
James Vaughn, MD	Pathologist (Educator)	07/20/2018	12/31/2021	Yes	Under 60 years, Non-Minority, Male, East
Andrew Stanton, CT	Cytotechnologist	06/15/2021	12/31/2024	Yes	Under 60 years, Non-Minority, Male, Middle
Matthew Hardison, PhD	Independent Lab Manager/Administrator	06/15/2021	12/31/2024	Yes	Under 60 years, Non-Minority, Male, Middle
Jennifer Gidcomb, MT	Medical Technologist	06/15/2021	12/31/2024	Yes	Under 60 years, Non-Minority, Female, West
Jerry Barker, MT	Hospital Administration	06/15/2021	12/31/2024	Yes	Under 60 years, Non-Minority, Male, West

4. Are there any vacancies on the board? If so, please indicate how long the position has been vacant and explain steps that have been taken to fill any vacancies.

   There are currently two (2) vacancies on the Medical Laboratory Board. The Laboratory Supervisor position has been vacant since April 30, 2021, due to resignation. The Non-Pathologist Physician position has been vacant since March 1, 2021, due to resignation. Notice was made to the Governor's Office and the vacancies are currently in the appointment process.

5. How many times did the board meet in each of the last two fiscal years?

   The Medical Laboratory Board met four (4) times in FY20. The Board met four (4) times in FY21.

6. How many members were present at each meeting? Please note meetings where the board did not have a quorum.

Fiscal Year 2020		
Meeting Date	**# Board Members**	**Quorum**
07/19/2019	8	Yes
10/17/2019	9	Yes
01/29/2020	12	Yes
04/27/2020	9	Yes

Fiscal Year 2021		
Meeting Date	**# Board Members**	**Quorum**
07/22-23/2020	12	Yes
10/22/2020	10	Yes
01/29/2021	12	Yes
04/29/2021	8	Yes

Financial Information

7. What were the board's revenues and expenditures for the last two fiscal years? Does the board carry a reserve balance? If so, please provide additional relevant information regarding the reserve balance, including whether the board is self-sufficient.

   For FY 2019, the Board had revenues of $657,226.56 and total expenditures of $609,825.72, with a reserve balance of $1,783,774.44.

   For FY 2020, the Board had revenues of $715,240.58 and total expenditures of $604,540.14, with a reserve balance of $1,842.329.27.

   The Board is self-sufficient.

8. Do board members receive per diem or travel reimbursements? How much was paid to individual board members in each of the last two fiscal years?

Board members do not receive a per diem. Travel reimbursements are paid according to the Department of Finance and Administration's Comprehensive Travel Regulations. The per diem and travel amounts for each Committee member listed below represents the amounts paid from July 1, 2018, through June 30, 2020.

Member Name	FY19-Per Diem Total	FY19-Travel Reimbursement Total	FY20-Per Diem Total	FY20-Travel Reimbursement Total
Lee Anne Briggs	$0	$1,213.64	$0	$1,048.59
Keisha Burnett	$0	$1,980.94	$0	$1,237.62
Mark Calarco	$0	$65.80	$0	$52.64
Tereyo Cox	$0	$240.64	$0	$890.48
Carla Davis	$0	$45.12	$0	$0
Paul Fleming	$0	$0	$0	$0
Danielle Gibson	$0	$18.80	$0	$56.40
Michael C. Johnson	$0	$180.48	$0	$180.48
Gaye Jolly	$0	$974.63	$0	$657.55
Jon Parham	$0	$501.96	$0	$334.64
Lynn Stewart	$0	$15.04	$0	$15.04
James Vaughan	$0	$935.32	$0	$1,610.56
Patti Walton	$0	$195.52	$0	$146.64

9. Does the board collect fees? If yes, provide relevant information about fees collected. Indicate whether fees were established through rule or through state law.

The Board has established rules with the authority granted by statute to collect fees. The following fees are collected:

Fee Category	Fee Amount	Rule or Statute
Initial Facility Licensure Fee-Medical Laboratory Facilities	$1,000	Rule
Initial Facility Licensure Fee-Collection Stations	$700	Rule
Initial Personnel Licensure Fee-Medical Laboratory Personnel	$50	Rule
Initial Training Program Licensure Fee-Laboratory Training Programs	$200	Rule
Annual Renewal Fee-Medical Laboratory Facilities	$1,000	Rule
Annual Renewal Fee-Collection Stations	$700	Rule
Biennial Renewal Fee – Medical Laboratory Personnel per Modifier	$90	Rule
Annual Renewal Fee-Laboratory Training Programs	$100	Rule
Late Renewal Fee Fee-Medical Laboratory Facilities	$500	Rule
Late Renewal Fees-Collection Station	$500	Rule
Late Renewal Fee-Medical Laboratory Personnel	$60	Rule
Duplicate License Fee – Medical Laboratory Facilities	$50	Rule
Replacement License Fee-Medical Laboratory Personnel	$40	Rule
Duplicate Certificate Fee-Medical Laboratory Personnel	$25	Rule
Change Fee for Directorship, Ownership & Location-Med Lab Facilities	$100	Rule
Annual State Regulatory Fee -Medical Laboratory Facilities	$5	Rule
Biennial State Regulatory Fee-Medical Laboratory Personnel	$10	Rule
Annual State Regulatory Fee-Laboratory Training Programs	$5	Rule

Sunshine Law, Public Meetings, and Conflict of Interest Policies

10. Is the board subject to Sunshine law requirements (Section 8-44-101 et seq., *Tennessee Code Annotated*) for public notice of meetings, prompt and full recording of minutes, and public access to minutes? If so, what procedures does the board have for informing the public of meetings and making minutes available to the public?

    The Board is subject to Sunshine law requirements of Tenn. Code Ann. 8-44-101 et seq. A public meeting notice is posted to the Board's website by the fifteenth (15^{th}) day of the month proceeding the month of the meeting date as well as posting the information on the Public Participation Calendar. The Board's administrative staff attends all meetings and takes minutes. Those minutes are then prepared for review and ratification by the Board at its next regularly scheduled meeting. After the minutes are ratified, they are then placed on the Board's website.

11. Does the board allow public comment at meetings? Is prior notice required for public comments? If public comment is not allowed, how does the board obtain feedback from the public and those they regulate?

    Board meetings are conducted in full view of the public pursuant to a sunshine notice, which provides information regarding the location, meeting time and topics to be

discussed. A live-streaming link is also included on the public notice to accommodate any members of the public that would like to view the meeting but are unable to travel to the meeting location. The meeting is guided by the published agenda. The Board will recognize members of the public who request to be heard on a matter properly noticed before the Board.

Additionally, all health related boards have instituted a sign-in sheet procedure at the meeting location that would permit members of the public to make time-limited comments on matters properly noticed and before the Board for consideration. Discussion of matters not receiving proper notice would violate the sunshine laws of Tennessee. Therefore, should a member of the public have a topic or comment that requires discussion, the most effective practice is to make the request known to the board director in advance to have the matter placed on the monthly sunshine notice. The Board also accepts and reviews letters as another means of addressing questions/concerns raised by the public and stakeholders. Meetings held virtually invite public comment during each meeting and recognize all listed attendees.

A video recording of the meeting is placed on the Board's website within 24-48 hours of the meeting and is also available on the Department's website for approximately one month following the meeting. An audio recording of the meeting is also available upon request.

12. Does the board have policies to address potential conflict of interest by board members, employees, or other state employees who work with the board?

Yes. All Board members are educated on the Department of Health's Conflict of Interest Policy and reminded during the course of each meeting of the obligation to strictly adhere to the policy. Board members are required to sign a Conflict of Interest Statement upon appointment or as soon as practical and annually thereafter. It is the responsibility of the Board Director to ensure that the Conflict of Interest Statement is properly and timely signed. Board staff is required to sign a new Conflict of Interest statement annually. The Board's Administrative Office keeps signed copies on file in the Central Office of Health Related Boards.

Licensure and Oversight Responsibilities

13. How many total licenses has the board had in each of the last two fiscal years?

In FY20, there were 99 laboratory directors, 1,445 laboratory supervisors, 250 special analysts, 1,919 medical laboratory technologists, 1,876 medical laboratory technicians, 361 laboratory facilities, and 22 laboratory training programs licensed.

In FY21, there were 117 laboratory directors, 1,545 laboratory supervisors, 280 special analysts, 2,116 medical laboratory technologists, 2,059 medical laboratory technicians, 367 laboratory facilities, and 23 laboratory training programs licensed.

14. How many new applications for licenses has the board received in each of the last two fiscal years? If necessary, please differentiate by type or category.

    In FY20, there were 346 new applications that included: 9 laboratory directors, 63 laboratory supervisors, 17 special analysts, 145 medical laboratory technologists, 93 medical laboratory technicians, and 19 laboratory facilities.

    In FY21, there were 583 new applications that included: 11 laboratory directors, 80 laboratory supervisors, 22 special analysts, 296 medical laboratory technologists, 152 medical laboratory technicians, 21 laboratory facilities, and 1 laboratory training programs.

15. How many license applications did the board deny during each of the last two fiscal years? What were the reasons for denial?

    During FY20 two (2) medical laboratory technicians were denied upgrading their license to medical laboratory technologists due to lack of a bachelor's degree.

    During FY21 no applications were denied.

16. What was the total number of complaints received by the board in each of the last two fiscal years? If available, please provide information on the number of consumer complaints as well as the number of administrative complaints.

    In FY20, there were five (5) new personnel complaints and ten (10) new facility complaints opened. There were three (3) administrative complaints against personnel and two (2) against facilities.

    In FY21, there was one (1) personnel complaint and thirteen (13) facility complaints opened. There were five (5) administrative complaints against facilities.

17. Section 69-29-106, *Tennessee Code Annotated*, authorizes the board to require the inspection of premises and operations of all medical laboratories subject to licensure. Please provide a brief description of the inspection process, including how results of inspections are reported to the board.

    The program area is assigned six (6) licensed medical laboratory professional consultants/surveyors, two (2) for each region of the state (East, Middle, and West). These six surveyors perform all initial and biennial surveys in Tennessee licensed facilities practicing laboratory medicine.

    All initial surveys are scheduled before the on-site review for licensure, and biennial surveys are always unannounced and again are performed in the physical location of the licensee.

The inspection process involves review of the testing menu as applicable to quality control variances with calibration/verification information for each instrument used in the evaluation of specimens submitted to the laboratory for analysis. The review involves compliance with patient test management, proficiency evaluations, alternate site testing review of tests performed outside of the laboratory by non-licensed laboratory personnel, and compliance with personnel requirements, with deficiencies issued from non-compliance with the Medical Laboratory Act.

Operations of laboratory medicine's scope of practice is reviewed for compliance with the promulgated rules and regulations pertaining to personnel and laboratories to include patient test management, quality control measures, guidelines for the performance of each category of laboratory medicine practices, review of proficiency testing technique with pass/fail review for each analyte tested.

Overall operation and appearance of the laboratory environment is reviewed for compliance with general health requirements concerning workspace, applied safety measures for working in a hazardous environment with possible issues that could endanger the general public and/or those individuals working in the laboratory, to include the appropriate disposal of waste materials and any sanitary conditions relative to the handling of human specimens.

Each surveyor performs a 100% audit of those working with laboratory materials and the employee roster is included in the survey report submitted to the program area for final review by the Program Director.

Should a facility be found out of compliance with the Medical Laboratory Act, the regional surveyor would issue a document with the deficiency(ies) on a Statement of Deficiencies document which is returned to the inspected facility with a set time for their Plan of Correction to be returned to the regional surveyor.

Deficiencies are always discussed on site with the laboratory administrator and/or director and facility administration during an exit conference for review of the survey findings and follow-up discussions concerning questions about the survey findings.

If no deficiencies are found during the survey, a letter stating compliance is mailed to the facility from the regional surveyor stating such and thanking them for their hospitality.

When completed, all regional survey kits are sent to the Board's Administrative Office for final review and capture in the Department of Health's electronic database.

Any questionable non-compliance issues are reviewed by the Board's Consultant and Board-assigned attorney for possible litigation.

18. Describe the process by which the board receives, handles, and tracks complaints. For example, are complaints rated by level of seriousness or other priority-handling method? Is a complaint log maintained? What benchmarks have been established for timely resolution of complaints? Are all complaints resolved timely?

    The Board receives complaints through the Office of Investigations. The Office of Investigations maintains a website with instructions of how to file a complaint. This website allows the public to provide complaints electronically, by phone, mail or fax. All complaints are entered into a database system upon receipt and are assigned to the Board's complaint coordinator. Each complaint is reviewed by the Board's consultant and attorney to determine if the allegation constitutes a violation of the Board's practice act and rules.

    If it is determined that the allegation would constitute a violation of the practice act or rules, the consultant and attorney will request that the allegation be investigated by a trained investigator with the Department of Health. Complaints that involve the potential for immediate jeopardy to the public are prioritized. All complaints have a 90- day benchmark for completion. Complaints are completed within the assigned benchmark when possible however 30-day extensions are granted in instances when additional time is needed to complete a thorough investigation due to issues such as witness availability and receipt of medical records from a third party.

    Once investigated, the investigative report and all evidence obtained are provided to the consultant and attorney where they review it together to determine if there is evidence to support the violation alleged by the complainant. If so, the consultant and attorney discuss the appropriate level of discipline that is proportionate to the violation and the licensee is provided with an opportunity to agree to that discipline. The licensee also has the right to reject the Board's proposed discipline and request a formal contested case hearing before the Board.

    Not all complaints are assigned for investigation. In instances where the consultant and attorney find that the complaint does not violate the practice act and investigation is not necessary, the file is closed, and the complainant is notified in writing. Complaints that fall outside the jurisdiction of the office of investigations are forwarded as appropriate.

19. Please describe how the board takes disciplinary action against those who are found to have violated statutes and/or the board's rules and regulations.

    If the consultant and attorney determine that the investigative report and evidence substantiate that a licensee has committed a violation of the practice act and/or rules that rises to the level of public discipline, the case will be transferred to the Office of General Counsel for prosecution. Formal discipline of a licensee can consist of a private censure, reprimand, probation, suspension, voluntary surrender, revocation and summary suspension. The licensee can also be assessed civil penalties that range from $50.00-$1,000.00 per violation; required to complete continuing education hours in addition to

those required to maintain licensure; and assessed the costs for the investigation and presentation of the matter.

There are several procedural avenues by which disciplinary matters may come before the Board:

Consent Orders— Presents the licensee an opportunity to resolve the matter by agreement, making formal proceedings unnecessary. By signing the Consent Order, the licensee waives the right to a contested case hearing and any and all rights to judicial review in the matter and agrees to the presentation and consideration of the Consent Order by the Board for ratification at the scheduled public meeting. After the Board approves the public disciplinary action, the Office of General Counsel sends a copy of the order to the Disciplinary Coordinator. The Disciplinary Coordinator changes the licensure status in the LARS database as appropriate, posts the disciplinary action on the public website for the health related boards, and reports the disciplinary action to the National Practitioner Databank. The Disciplinary Coordinator also monitors the case as appropriate to ensure that the Respondent complies with the terms of the order and reports the action on the monthly disciplinary action report. Should the Board fail to ratify the Consent Order, formal disciplinary proceedings will be initiated, and the licensee is notified of such.

Agreed Orders— When a licensee has requested a formal disciplinary hearing in lieu of settling the matter by Consent Order and then requests to settle the matter prior to the formal proceeding taking place, an Agreed Order allows the licensee to waive the right to a contested case hearing and any and all rights to judicial review in the matter. The Agreed Order is presented to the Board for ratification at the scheduled public meeting. After the Board approves public disciplinary action, the Office of General Counsel sends a copy of the order to the Disciplinary Coordinator. The Disciplinary Coordinator changes the licensure status in the LARS database as appropriate, posts the disciplinary action on the public website for the Health Related Boards, and reports the disciplinary action to the National Practitioner Databank. The Disciplinary Coordinator also monitors the case as appropriate to assure that the Respondent complies with the terms of the order and reports the action on the monthly disciplinary action report. Should the Board fail to ratify the Agreed Order, formal disciplinary proceedings will be initiated, and the licensee is notified of such.

Contested Cases— Formal disciplinary hearings in which the Board sits as jury. An Administrative Law Judge presides and makes evidentiary rulings and instructs the Board as to procedure. Board members may question witnesses. The licensee, known as the "Respondent," is prosecuted by a litigating attorney from the Office of General Counsel who represents the State, just as a prosecutor in a criminal court represents the State. A licensee always has the right to legal counsel.

20. How many licenses did the board revoke or suspend during each of the last two fiscal years? What were the reasons for the revocations or suspensions?

    There were no licenses revoked or suspended by the Board during the last two (2) fiscal years.

21. Does the board maintain reciprocal agreements with other states to recognize associated professions who are licensed under the laws of other states such that these individuals may practice in Tennessee?

    The Board does not maintain reciprocal agreements with any other states.

Reports, Major Accomplishments, and Proposed Legislative Changes

22. What reports does the board prepare concerning its activities, operations, and accomplishments? Who receives copies of these reports? Please provide a link to any such reports issued in the last two fiscal years.

    At every Board meeting, the Board Director's report is presented that details the activities performed during the prior quarter. The details of this report are included in the Board's meeting minutes. The meeting minutes are available online for the public.

23. What were the board's major accomplishments during the last two fiscal years?

    Rewrite of the Rules and Regulations Governing Medical Laboratory Personnel 1200-06-01, which are currently in the review process by the Secretary of State's Office in preparation for a future rulemaking hearing.

    Implemented the online application process for laboratory facilities and personnel.

    The Board, in conjunction with Communicable and Environmental Diseases and Emergency Preparedness Division (CEDEP), are collaborating on building a database in which to better communicate with all laboratories across the State.

    Developed a policy statement regarding restricted laboratory supervisor licensure in thirty (30) bed or less facilities to assist rural Tennessee hospitals with staffing.

    The Board continued to successfully hold meetings during a pandemic. Board members successfully held virtual meetings and ensured that the public had access to view and participate in those virtual board meetings.

24. What, if any, challenges has the board addressed in the last two fiscal years?

Fiscal year 2020 presented challenges for the Board, as a result of the March tornadoes and the COVID-19 pandemic. Fiscal year 2021 continued to be a challenge due to the ongoing pandemic. These challenges and their resolutions have included:

1) Hesitancy and concern from board members over conducting board/committee meetings via an in-person format, due to their own personal high-risk status or travel/overnight stay concerns during the pandemic.
    a. Executive Order #16 and subsequent extensions, allowing for meetings to be held via remote teleconference means, provided the resolution required for this challenge.
2) Medical laboratory directors and laboratory personnel began to work remotely due to limiting their exposure and personal risk to COVID-19. The Board provided guidance to laboratories transitioning to remote work while remaining compliant with the Board's regulations.
    a. Executive Order #36 and the subsequent extensions provided the resolution required for this challenge.

3) During the ongoing COVID-19 pandemic, the Board had to give technical advice to laboratories regarding the rapidly changing testing technology. There was an influx of testing laboratories that required updates to their licenses to allow for the performance of COVID-19 testing.

4) The Board acted as a liaison between laboratories and their temporary unlicensed workforce in an effort to assist with staffing shortages. They developed policies to address testing supply shortages, mobile laboratories, and remote laboratory work (telemedicine).

5) The Board continues to address ongoing testing issues that arise related to the newly developed technology to ensure quality laboratory testing for all Tennesseans.

25. Please describe any items related to the board that require legislative attention and your proposed legislative changes.

    There are no legislative changes needed at this time.

26. Should the board be continued? To what extent and in what ways would the absence of the board affect the public welfare of the citizens of Tennessee?

    Yes, the Medical Laboratory Board should continue to protect the citizens of Tennessee by ensuring quality laboratory practices through the licensure of laboratory personnel, facilities and training programs. Laboratory reports are a major contribution in the evaluation of an individual's overall health assessment and provide an invaluable tool in the diagnosis and prognosis of that individual's healthcare as well as a roadmap of information for the clinician in assessing treatment. The information utilized by the

practitioner must have been processed with optimal integrity related to best practices of laboratory medicine. The values assigned to the individual's laboratory report provide a valuable tool to the health care provider in the establishment of disease patterns and the appropriate method of diagnosis for the concerned individual.

27. Please identify the appropriate agency representative or representatives possessing substantial knowledge and understanding of the responses provided to the sunset review questions.

    Brent Culberson, Assistant Commissioner, Legislative Affairs
    Elizabeth Foy, Legislative Liaison
    Jennifer Putnam, Assistant Commissioner, Health Licensure and Regulation
    Alicia Grice, Fiscal Director, Health Licensure and Regulation
    Sandra Bogard, Board Director
    Mark Cole, Senior Associate Counsel
    LeeAnne Briggs, Board Member

28. Please identify the appropriate agency representative or representatives who will respond to the questions at the scheduled sunset hearing.

    Jennifer Putnam, Assistant Commissioner, Health Licensure and Regulation
    Elizabeth Foy, Legislative Liaison
    Alicia Grice, Fiscal Director, Health Licensure and Regulation
    Sandra Bogard, Board Director
    Mark Cole, Senior Associate Counsel
    LeeAnne Briggs, Board Member

29. Please provide the office address, telephone number, and email address of the agency representative or representatives who will respond to the questions at the scheduled sunset hearing.

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